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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,458	01/28/2004	Lawrence E. Thibault	B1206/20001	3169

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CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.
11TH FLOOR, SEVEN PENN CENTER
1635 MARKET STREET
PHILADELPHIA, PA 19103-2212

EXAMINER	
ROY, ANURADHA	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,458	THIBAULT ET AL.	
	Examiner	Art Unit	
	Anuradha Roy	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-11, 14, & 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by John (US Patent No. 3,901,215).

Regarding claim 1, John discloses a method for determining the severity of brain function impairment in a person due to an insult to said brain such as mild traumatic brain injury, aging or intoxication, comprising the steps of:

(a) determining a processing time value (Column 1, lines 61-63 & 12) of said person in accordance with an elapsed time between a stimulus applied to said person and a response to said stimulus provided by said person, wherein said processing time value is representative of said impaired brain function (Column 7, line 60 – Column 8, line 3 – Examiner contends that there is inherently a

processing of response time to stimuli since there is an EEG used to record brain activity during each response);

(b) providing electrical signals (Column 1, line 61 – Column 2, line 7 & Figure 3) in accordance with said processing time value, whereby said electrical signals are representative of said impaired brain function;

(c) performing mathematical operations (Column 1, line 61 – Column 2, line 7) upon said electrical signals to provide a processing time index;

(d) determining said severity of said brain function impairment (Column 1, line 68 – Column 2, line 5 & Column) in accordance with said processing time index (Column 10, lines 28-45).

Regarding claim 2, John discloses a method for determining the severity of brain function impairment in a person, comprising the further step of determining concussion severity in accordance with said processing time index (Column 1, lines 32-35). Examiner contends the aforementioned method is capable of determining the severity of a concussion since it is capable of discerning other brain impairments.

Regarding claims 5, 6, 7, 8, & 9, John discloses a method for determining the severity of brain function impairment in a person, comprising the further steps of: applying a visual stimulus to a person (Column 1, lines 11-14 & Figure 7); applying an

audio stimulus to a person (Column 1, lines 11-14 & Column 7, line 67 – Column 8, line 3); (a) applying a somatosensory stimulus to a person (Column 1, lines 11-14 & Column 2, lines 9-27 & Column 3, lines 55-58); and determining said severity of said brain function impairment in accordance with said audio stimulus, said visual stimulus and said somatosensory stimulus (Column 1, lines 32-35).

Regarding claim 10, 11, & 14, John discloses a method for determining the severity of brain function impairment in a person of claim 5, comprising the further steps of: determining a response to a visual stimulus (Column 7, lines 61-63 & Column 8, lines 50-59) from said person; determining a processing time value in accordance with a time elapsed between the time of applying of a visual stimulus to a person and the time of a determining of said response to a visual stimulus (Column 9, lines 33-44); determining a response to a audio stimulus (Column 7, lines 61-63 & Column 8, lines 50-59) from said person; determining said processing time value in accordance with a time elapsed between the time of said applying of said audio stimulus to said person and the time of said determining of said response to said audio stimulus (Column 7, line 64 – Column 8, line 5); determining a response to said somatosensory stimulus (Column 9, lines 55- 56) from said person; and determining said processing time value in accordance with a time elapsed between said applying of said somatosensory

stimulus and said response to said somatosensory stimulus (Column 9, line 56 – Column 10, line 7).

Regarding claims 23 & 24, John discloses a method for determining the severity of brain function impairment, which inherently involves comparing said processing time index with a value representative of a population norm and thus determining a status of said person in accordance with said comparing (Figure 3 & Column 2, lines 2-4).

Regarding claim 25, John discloses a method for determining the severity of brain function impairment in a person, comprising the further step of comparing said processing time value with a previous processing time value of said individual (Column 11, lines 11-14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 & 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over

John in view of Carter (US Patent No. 5,892,568).

John discloses the aforementioned steps of a method for determining the severity of brain function impairment in a person. However, John does not disclose determining said severity of said brain function impairment using pupillometry and a hand held pupillometer. Carter, however, discloses the use of a hand held pupillometer (Figure 1A & 1B). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Carter to use a hand held pupillometer with John in order to diagnose brain impairments, such as Alzheimer' s disease.

Additional Claim Rejections - 35 USC § 103

Claims 12 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Boyd et al. (US Publication No. 200 4/0229198).

Although John discloses the method mentioned above, Jones does not discloses the further steps of: (a) applying a first plurality of unfilled geometric shapes to said person; (b) applying a second plurality of filled geometric shapes to said person; (c) determining a response to said applying of said second plurality of filled geometric shapes; and (d) determining said processing time value in accordance with a time elapsed between said applying of said second plurality of filled geometric shapes to said person and said response to said applying of said second plurality of geometric shapes.

However, Boyd et al. discloses a method of: (a) applying a first plurality of unfilled geometric shapes ([0028], [0061], [0068], & [0069]); (b) applying a second plurality of filled geometric shapes to said person ([0028], [0061], [0068], & [0069]); (c) determining a response to said applying of said second plurality of filled geometric shapes (Abstract, [0081], [0082], & [0068]); and (d) determining said processing time value in accordance with a time elapsed between said applying of said second plurality of filled geometric shapes to said person and said response to said applying of said second plurality of geometric shapes (Abstract, [0081], [0082], & [0068]). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Boyd et al. to apply filled and unfilled geometric shapes to a person and determine the processing time value with John in order to further evaluate brain function impairments.

John in view of Boyd et al. discloses the claimed invention but does not disclose expressly that the second plurality of filled geometric shapes is smaller than said first plurality of unfilled geometric shapes. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by John in view of Boyd et al. with the second plurality of filled geometric shapes is smaller than said first plurality of unfilled geometric shapes, because Applicant has not disclosed that the second plurality of filled geometric shapes is smaller than said first plurality of unfilled geometric shapes provides an advantage, is used for a particular purpose, or

solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with an unspecified plurality of filled and unfilled shapes as taught by John in view of Boyd et al., because it would serve the same purpose of determining brain function impairments and since it appears to be an arbitrary design consideration which fails to patentably distinguish over John in view of Boyd et al.

Therefore, it would have been an obvious matter of design choice to modify John in view of Boyd et al. to obtain the invention as specified in the claim(s).

Additional Claim Rejections - 35 USC § 103

Claims 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Carey (US Patent No. 4,885,687).

John discloses a method for determining the severity of brain function impairment in a person with all of the previously mentioned elements. However, John does not disclose the further step of determining processing time value in accordance with a tracking of the motion of a moving target by a person. Carey, however, discloses a method capable of determining the severity of a brain function impairment comprising the step of determining processing time value in accordance with a tracking of the motion of a moving target by a person (Column 4, lines 8-24). It would have been

obvious to one having ordinary skill in the art at the time the invention in view of Carey to incorporate a step determining said processing time value via a tracking of the motion of a moving target with John in order to further evaluate any brain function impairments of a person.

In regards to claim 16, John in view of Carey further discloses a method for determining the severity of brain function impairment in a person comprising the further step of determining said processing time value in accordance with the ability of said person to track said motion of said moving target with a cursor (Column 4, lines 18-24) controlled by a manual control device (83 & Column 4, lines 18-24) when said moving target is displayed on a video display (80).

Regarding claim 17, John in view of Carey further discloses a method, wherein motion of moving target (Column 14, line 14) comprises an inherent step function stimulus (Column 4, lines 13-16) having a predicted response (Column 4, line 20) and an elicited response (Column 4, line 19) from said person.

Furthermore, regarding claim 18, John in view of Carey discloses a method wherein said elicited response comprises a damped oscillatory response (Column 4, lines 16-21). Examiner contends that a reduction to practice suggests a target and traced pattern, or the elicited response, could be capable of incorporating a damped oscillatory response.

With regard to claims 19-21, John in view of Carey discloses a method inherently comprising the further step of determining a delay time value (Column 4, lines 21-22) and a rise time value (Column 4, lines 21-24) in accordance with said damped oscillatory response. As a result, John in view of Carey discloses a method comprising the further step of determining said processing time value (Column 4, lines 21-22 & 55-57) in accordance with said delay time value and said rise time value (Column 4, lines 21-24 & 52-57).

Regarding claim 22, John in view of Carey discloses a method capable of determining the severity of brain function impairment, comprising the further steps: (a) disposing said cursor within said target (Column 4, lines 13-16) (b) applying a forcing function to said target to cause said target to move on said display (Column 4, lines 16-18); (c) instructing said person to use said manual control device to move said cursor on said display and maintain said cursor within said moving target while said target is in motion (Column 4, lines 18-21); and (d) determining said processing time value in accordance with the amount of time said person maintains said cursor within said moving target (Column 4, lines 21-24).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. John et al. (US Patent No. 6,385,486 & US Publication No.

2002/0091335) disclose a brain function assessment system with aural and sensory stimuli. McKinnon et al. (US Patent No. 6,474,817) & Pope et al. (US Patent No. 5,377,100) discloses a method for testing brain function impairments with visual testing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner' s supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700